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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 445,223	12 06 1999	DAVID WALLACH	WALLACH 24	9660

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EXAMINER

DAVIS, MINH TAM B

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 11 05 2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/445,223

Applicant(s)

WALLACH ET AL.

Examiner

MINH-TAM DAVIS

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 22 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) 5-8, 11, 14, 15, 22-24, 29, 30, 40-49 and 51-53 is/are pending in the application.
- 4a) Of the above claim(s) 14, 15, 22, 29, 30, 40-43 and 49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) 5-8, 11, 23 and 44-48 is/are allowed.
- 6) ☐ Claim(s) 24 and 51-53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Effective February 7, 1998, the Group Art Unit location has been changed, and the examiner of the application has been changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Minh-Tam Davis, Group Art Unit 1642.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### **RESTRICTION**

Applicant argues that claims 40-43, drawn to the B1 protein should be rejoined with the encoding polynucleotide, according to example 17 of Annex B, Part II of MPEP 1893.03(d). Applicant further asserts that claim 49, which is a method of use of the B1 protein should therefore also be rejoined with the claimed polynucleotide. Applicant asserts that since claims 14 and 15 are dependent on claim 49 (formerly claim 13), claims 14 and 15 should also be examined. Further, Applicant asserts that since the Examiner has considered that claims 29 and 30 are patentably indistinct from claim 13, now claim 49, these should also be examined in the present application.

Applicant's arguments set forth in paper No.13 have been considered but are not deemed to be persuasive for the following reasons:

Claims 40-43, drawn to the B1 protein, are not rejoined with the claims drawn to the encoding polynucleotide, because of the following reasons: Annex B, Part II of MPEP 1893.03(d) only discloses an example, example 17, stating that the protein and

the encoding DNA sequence exhibit corresponding special technical features, and that unity between protein X and DNA sequence encoding protein X is accepted. However, since it is only an example, there is no indication or disclosure that it is a requirement to consider protein X and the encoding DNA sequence together, especially in view of the fact that the protein and the encoding DNA sequence do not share a common structure. Further, claim 49 is not considered, since the B1 protein is not rejoined with the encoding polynucleotide, and since claim 49 is a method of use of the B1 protein, and thus constitutes an additional method, which does not share the same technical feature with the elected first method of use of the claimed polynucleotide. In addition, claims 14 and 15 belong to group V which is an additional method of use of the claimed polynucleotide, and thus are not considered. Moreover, similar to claim 49, claims 29 and 30 of group IV, drawn to methods of use of the B1 protein are not considered because claim 49, drawn to a method of use of the B1 protein is not considered. Claims 29 and 30 of group V are drawn to an additional method of use of the claimed polynucleotide, and thus are not considered.

The requirement is still deemed proper, and was made FINAL, for reasons set forth above and in previous Office action.

Applicant adds new claims 52, 53 which are related to claims 5-8, 11, 23, 24, 44-48, and 51.

Accordingly, claims 5-8, 11, 23, 24, 44-48, 51-53 are being examined.

Claims 5-8, 11, 23, 44-48 are free of prior art and are allowable.

The following are the remaining rejections.

Art Unit: 1642

**REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, NEW MATTER, NEW  
REJECTION**

Claims 24, 51-53 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 24, and 51-53 are drawn to an oligonucleotide molecule "consisting of" a sequence "encoding" an antisense sequence of at least part of an mRNA sequence corresponding to a DNA sequence comprising SEQ ID NO:1, or an analog or a fragment thereof which analog or fragment thereof potentiates cell death.

The specification does not disclose an oligonucleotide molecule "consisting of" a sequence "encoding" an antisense sequence of at least part of an mRNA sequence corresponding to a DNA sequence comprising SEQ ID NO:1, or an analog or a fragment thereof which analog or fragment thereof potentiates cell death.

**REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, ENABLEMENT, NEW  
REJECTION**

Claims 24, 51-53 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.



Claims 24, and 51-53 are drawn to an oligonucleotide molecule consisting of a sequence "encoding" an antisense sequence of at least part of an mRNA sequence corresponding to a DNA sequence comprising SEQ ID NO:1, or an analog or a fragment thereof which analog or fragment thereof potentiates cell death.

It is notoriously well known in the art that a triplet codon represents an amino acid. In other words, an oligonucleotide sequence encodes only a peptide sequence, and it does not encode an antisense sequence, which is another oligonucleotide sequence.

Without a teaching of how to make a sequence "encoding" an antisense sequence of at least part of an mRNA sequence corresponding to a DNA sequence comprising SEQ ID NO:1, or an analog or a fragment thereof which analog or fragment thereof potentiates cell death, one of skill in the art does not know how to make the claimed sequence.

In view of the above, it would have been undue experimentation for one of skill in the art to make and use the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 703-305-2008. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANTHONY CAPUTA can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-

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872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

MINH TAM DAVIS

October 31, 2002

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